No. 1:17-md-02775

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

IN RE SMITH & NEPHEW BIRMINGHAM HIP RESURFACING (BHR) HIP IMPLANT PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO
BHR TRACK Cases Identified in Exhibit A to D.E. 3304-1

DEFENDANT SMITH & NEPHEW, INC.'S REPLY IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT AS TO ALL CLAIMS OF PLAINTIFFS WITH IMPLANT DATES PRIOR TO OCTOBER 2009

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INTRODUCTION AND SUMMARY

During the nearly five years of pre-trial proceedings, including wide-ranging discovery, multiple expert reports, and motions practice setting the boundaries for claims and evidence in the BHR track, Plaintiffs have made Australian "ad hoc" registry data central to their claims. In *Redick*, the first bellwether trial, Plaintiffs' "theory of the case" was that "by touting publicly available reports from international registries containing clinical results from hip implant surgeries which showed excellent and market leading success rates for the BHR," Smith & Nephew' statements were ***misleading*** because the company had non-public "ad hoc" data that Plaintiffs claimed "showed ***significantly worse success rates for the BHR*** in women and patients with small head sizes." *Redick* Mem. [D.E. 2715] (May 17, 2021) at 2; (emphasis added); *accord Sedgwick* Mem. [D.E. 2977] (Aug. 19, 2021) at 2.[1]

Faced with a summary judgment motion directed at Plaintiffs who had their BHR implant surgeries ***before*** Smith & Nephew had received any relevant ad hoc data, Plaintiffs make an abrupt about-face. Plaintiffs now contend ad hoc data are irrelevant, and affirmatively assert there is no "***significant difference between the ad hoc data and the publicly reported registry data***." Plaintiffs' Response to S&N's Motion for Summary Judgment [D.E. 3477] ("Resp." or "Response") at 3 (emphasis added). Plaintiffs argue for the first time that the ad hoc reports merely "confirmed" public information that Smith & Nephew and "everybody 'already knew.'" *Id.* at 10. Failure to publicize information that Plaintiffs argue "everybody 'already knew'" cannot support

[1] The same is true of the two other original bellwether selections. *Mosca* Mem. [D.E. 2905] (July 19, 2021) at 3 ("Ms. Mosca . . . contends that by failing to incorporate its knowledge of the ad hoc data into its BHR marketing efforts and instead highlighting overall BHR revision rates, [S&N] misleadingly represented . . . the risk of revision"); *Albritton* Mem. [D.E. 2962] (Aug. 13, 2021) at 12 ("Mr. Albritton contends that ad hoc reports from the Australian registry [S&N] received following Mr. Albritton's surgery in 2009 showed an even greater magnitude of revision risk for patients with AVN.").

a claim for misrepresentation, and thus Plaintiffs' abandonment of their prior "theory of the case" cannot avoid summary judgment as to Plaintiffs with BHR implants before October 2009.

Ad hoc reports have been central to Plaintiffs' litigation of the BHR track because FDA's pre-market approval of the BHR restricts the grounds for possible recovery. Federal law expressly preempts all claims against Smith & Nephew (i) for failure to warn patients or the medical community, (ii) for making statements consistent with (or verbatim from) the BHR labeling because such statements have been "blessed" by FDA, and (iii) for claims that would undermine the FDA's "PMA approval process." *Sedgwick* Mem. [D.E. 2977] at 18. Here, ad hoc reports are irrelevant to the claims by Plaintiffs with BHR implants prior to October 2009, ***before*** the receipt of relevant ad hoc data. Plaintiffs have identified no alternative theory that can support liability.

First, summary judgment should be granted because Plaintiffs have identified no "potentially actionable misrepresentations that would be applicable to all patients generally." Memorandum [D.E. 3496] (Feb. 28, 2022). Plaintiffs point to no representations made to surgeons prior to October 2009 that can support liability. Plaintiffs already have conceded that there is "nothing misleading" about the first Dear Doctor letter Smith & Nephew sent to surgeons in November 2007 concerning the Australian Registry's 2007 Annual Report. *See* Smith & Nephew Memorandum in Support of Summary Judgment [D.E. 3304-1] ("SJ Mem.") at 23-24. Likewise, as to the May 2009 Pseudotumor letter, Plaintiffs identify no misrepresentations, and, in fact, the letter explains that "[t]he exclusive finding of 'pseudo-tumors' in female patients could be interpreted as a gender-specific higher susceptibility to metal ion hypersensitivity and stronger immune response." *Id.* at 24-25. Finally, Plaintiffs have no claim as to the Patient's Guide. Its description, inter alia, of the benefits of "as-cast" metallurgy fails here because the Court has held that "it was not until 2015 that Smith & Nephew received data that undercut its assertions that the

BHR's 'as-cast' metallurgy was responsible for a revision rate that was lower than its heat-treated competitors." *Sedgwick* Mem. [D.E. 2977] at 18.

Second, Plaintiffs fail to submit any evidence tying any of these theories of liability to the specific Plaintiffs whose claims are at issue. Even if they could, Plaintiffs' legal theories are impermissible claims that (i) challenge FDA's approval of the BHR, or (ii) are based on statements that were "blessed" by FDA in the BHR label. At bottom, the arguments advanced by Plaintiffs are failure to warn claims, *i.e.*, that Smith & Nephew was aware of certain information based upon review of publicly available data, and failed to share that information with the medical community.

Finally, Plaintiffs do not respond meaningfully to Smith & Nephew's showing that summary judgment should be granted on their remaining claims for compensatory and punitive damages. Summary judgment should be granted under Rule 56(c). *See* Mem. [D.E. 3496] at 5-6.

ARGUMENT

I. PLAINTIFFS' RESPONSE IS PROCEDURALLY IMPROPER AND FAILS TO MEET THE REQUIREMENTS OF RULE 56.

Smith & Nephew's Memorandum in Support of Summary Judgment showed that Plaintiffs with early implant dates have failed to adduce evidence to support essential elements of their claims. SJ Mem. at 1. As to Plaintiffs' core claims of misrepresentation and breach of warranty, Smith & Nephew showed that Plaintiffs have not identified negligent misrepresentations made by Smith & Nephew to Plaintiffs or their physicians prior to their implant surgeries. *Id.* at 18-25. In their Response, Plaintiffs make no effort to identify any causal link between any alleged negligent misrepresentation or breach of express warranty and the claims of any specific plaintiff. Indeed, Plaintiffs have submitted no affidavits from Plaintiffs or their physicians to satisfy this essential element of their claims. Resp. at 5.

Under Rule 56, to avoid summary judgment, Plaintiffs have the burden of submitting evidence that there is a triable issue of fact. *See* Fed. R. Civ. P. 56(c). Further, under Rule 56(d), to defer a ruling on a motion for summary judgment pending further discovery, Plaintiffs must "show[] by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition." Fed. R. Civ. P. 56(d).[2] Plaintiffs do not even attempt to meet this standard. Instead, Plaintiffs "adopt and incorporate" their prior argument that summary judgment is categorically not appropriate in an MDL before each plaintiff has "had the opportunity to engage in full discovery on their cases." Resp. at 5. But that is incorrect as a matter of law and well-settled MDL practice. *See* Mem. [D.E. 3496], at 4. Summary judgment is appropriate "*at any time* until 30 days after the close of all discovery," Fed. R. Civ. P. 56(b) (emphasis added); no statute, rule, or decision displaces that rule in the MDL context. As the Fourth Circuit recognized, "[i]t is well established that a transferee court may dispose of cases in an MDL through summary judgment—and indeed, they often do." *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig. (No. II) MDL 2502*, 892 F.3d 624, 648 (4th Cir. 2018); *accord In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig.* (*No. II*), 387 F. Supp. 3d 323, 358 (S.D.N.Y. 2019) (granting summary judgment against "approximately 920 plaintiffs in this MDL"), *aff'd,* 982 F.3d 113, 121 (2d Cir. 2020). For that reason, courts routinely hold MDL plaintiffs to the exacting

[2] The Fourth Circuit has explained that Rule 56(d) requires Plaintiffs to "set out the reasons for discovery in an affidavit, and [they] cannot withstand a motion for summary judgment." *Nader v. Blair*, 549 F.3d 953, 961 (4th Cir. 2008); *accord, e.g.*, *Harris v. Wash. Metro. Area Transit Auth.*, 544 F. Supp. 3d 53, 62 (D.D.C. 2021) (requiring Rule 56(d) affidavit to show "the particular facts the party opposing summary judgment intends to discover and describe why those facts are necessary to the litigation") (cleaned up). The required affidavit may not simply "demand discovery for the sake of discovery," but must demonstrate that the discovery sought is "essential to [the] opposition." *Bryant-El v. Rose*, No. CV CCB-18-0084, 2019 WL 1386728, at *3 (D. Md. Mar. 27, 2019) (alteration in original). Unsworn statements in a response brief are "not an adequate substitute for a Rule 56(d) affidavit." *Dave & Buster's, Inc. v. White Flint Mall, LLLP*, 616 F. App'x 552, 561 (4th Cir. 2015) (cleaned up).

standards of Rule 56(d)—and, indeed, have even recognized that it will be harder to show the need for additional discovery in a developed MDL where "many hundreds of thousands of pages of documents have been produced." *In re Avandia Mktg., Sales Pracs. & Prods. Liab. Litig.*, No. 07-MD-01871, 2012 WL 3205620, at *4 (E.D. Pa. Aug. 7, 2012) (rejecting argument that summary judgment should be deferred pending "individualized discovery"); *see also McKay v. Novartis Pharm. Corp.*, 751 F.3d 694, 700 (5th Cir. 2014) (affirming MDL judge's denial of request for additional discovery under Rule 56(d)).

Plaintiffs offer to supply "individualized affidavits from each and every plaintiff specifically mentioned by Smith & Nephew" if the Court believes such affidavits to be necessary, Resp. 5, but this is too little too late. Under Rule 56, such affidavits were necessary to satisfy Plaintiffs' burden, and an unsworn and conclusory attorney statement that they *could* supply the required affidavits, with additional time, is insufficient under Rule 56(d). If a party opposing summary judgment could defer an adverse ruling simply by averring to the possibility that it *could* supply evidence in the future, Rule 56(d) would be a dead letter. Rule 56(d) explains what a party must do to defer a summary judgment ruling, and Plaintiffs fail to meet that standard.[3]

Further, there is no reason to think these hypothetical affidavits would be sufficient because Plaintiffs fail to explain *what* information they would supply with additional time and *why* that information requires additional discovery. *See Harris*, 544 F. Supp. 3d at 62 n.6 ("[A] party seeking to avoid summary judgment under Rule 56(d) must show not only that the information she seeks is discoverable, but also that she 'could not produce the facts' without first obtaining

[3] In its ruling on Smith & Nephew's motion for summary judgment on male, large femoral plaintiffs [D.E. 3496], the Court declined to require submission of affidavits, observing that this could lead to having to decide hundreds of "175 individual summary judgment motions." *Id.* at 5. But there are other ways to address this problem, such as requiring affidavits, on a rolling basis, from a subset of the Plaintiffs or targeted discovery addressed to certain categories of cases.

discovery."). To the extent Plaintiffs' counsel want more time to interview their clients, Rule 56(d) is not an appropriate vehicle to gather additional facts from a party's "own witnesses," because those facts can be gathered without additional discovery. *See Strag v. Bd. of Trs.*, 55 F.3d 943, 954 (4th Cir. 1995); *see also, e.g.*, *Deal v. Tugalo Gas Co.*, 991 F.3d 1313, 1324 (11th Cir. 2021) (affirming denial of Rule 56(d) request where plaintiff sought to take discovery on alleged misrepresentations, which "would have been in [their] possession, obviating the need for additional discovery").[4]

Finally, Plaintiffs' Response fails to address many of the legal arguments advanced in Smith & Nephew's motion, instead including a boilerplate incorporation of "all of their briefing," without any explanation of which specific arguments are being incorporated, how the Court previously ruled on those arguments, or how those prior arguments apply to the specific issues raised in Smith & Nephew's Motion. This is improper. On summary judgment, a court is not required to "scour the record" to find the bases for a party's position. *See Jurgensen v. Albin Marine, Inc.*, 214 F. Supp. 2d 504, 510 (D. Md. 2002). Where a party incorporates arguments by reference, the incorporation "must be direct and explicit, in order to enable the responding party to ascertain the nature and extent of the incorporation." *Hinton v. Trans Union, LLC*, 654 F. Supp. 2d 440, 446 (E.D. Va. 2009) (quoting 5A Charles Alan Wright & Arthur R. Miller, Federal Practice

[4] Plaintiffs' request for more time is ill-taken here because, at the January 5, 2022 status conference, the Court asked Plaintiffs how long they needed to respond to the motion. Plaintiffs asked that the deadline occur after they submitted expert reports in the *Quirk* and *Hand* cases, and then later agreed to a February 15th due date. By that time, Smith & Nephew had already filed its reply in support of its motion for summary judgment for cases brought by male plaintiffs with large femoral head sizes, where Smith & Nephew set forth what Rule 56(d) and the Fourth Circuit require for a party to obtain pre-summary judgment discovery. *See* [D.E. 3323] at 2–7. Plaintiffs cannot now claim they were not supplied with enough time to meet the basic requirements of Rule 56(d) when they received the very deadline they ask for, nor can they claim to be surprised by Smith & Nephew's position when the parties had already fully briefed this issue.

& Procedure § 1326 (3d ed. 2004)); *cf. Kinder v. White*, 609 F. App'x 126, 132 (4th Cir. 2015) ("It is not the practice of this court to consider an argument that has not been developed in the body of a party's brief or identified in the headings."), *aff'd*, 382 F. App'x 256 (4th Cir. 2010). Plaintiffs cannot incorporate by reference the entirety of the voluminous briefing record in this litigation. In the sections that follow, Smith & Nephew responds to the arguments actually raised in the Response. All other arguments purportedly incorporated by reference should be deemed waived. *See Cox v. SNAP, Inc.*, 859 F.3d 304, 308 n.2 (4th Cir. 2017) ("If a party fails to assert a legal reason why summary judgment should not be granted, that ground is waived"); Mem. [D.E. 3496] at 5-6 (same); *Ferdinand-Davenport v. Children's Guild*, 742 F. Supp. 2d 772, 777 (D. Md. 2010) (Blake, J.) (similar).

II. SUMMARY JUDGMENT SHOULD BE GRANTED ON THE NEGLIGENT MISREPRESENTATION AND BREACH OF EXPRESS WARRANTY CLAIMS.

Plaintiffs contend that summary judgment should be denied as to their misrepresentation and breach of express warranty claims because Smith & Nephew was aware of an "increased revision risk in women and smaller head sizes" as early as 2006, Resp. at 7, and that Smith & Nephew "failed to include this in any voluntary communications it made to surgeons." *Id.* Apart from a passing reference in the Response, *id.* at 11, Plaintiffs ignore that the Court rejected essentially the same argument in *Sedgwick*. Indeed, the case for summary judgment is even stronger here because Plaintiffs have failed to identify any viable misrepresentations or breaches of express warranty by Smith & Nephew to Plaintiffs or their implanting surgeons.

A. Plaintiffs' Misrepresentation and Breach of Express Warranty Theories Are Preempted by Federal Law.

In *Sedgwick*, the Court granted summary judgment because Plaintiff failed to present sufficient evidence that Smith & Nephew had made any negligent misrepresentations to Mr. Sedgwick or his implanting physician. *Sedgwick* Mem. [D.E. 2977] at 16. The Court agreed that

the alleged misrepresentations could not support liability because they were "(1) consistent with the FDA label at the time of Mr. Sedgwick's surgery, and thus the Court's preemption ruling shields them from liability regarding those statements, or (2) not false or misleading because Smith & Nephew knew them to be true or believed them to be true at the time of Mr. Sedgwick's surgery." *Id.* at 17. Specifically, "representations that the five-year revision rate of the BHR was one to three percent overall were consistent with information contained within the BHR's FDA label at the time of [the implant] surgery." *Id.* Likewise, the Court rejected reliance upon pre-PMA approval data from before 2006 reflecting revision rates higher than the "one to three percent revision rate" that appeared in the BHR label because that theory of liability would "undermine the [FDA's] PMA approval process and the FDA-approved BHR label which contained and 'blessed' those revision rates." *Id.* at 18 (citing *Wildman v. Medtronic, Inc*., 874 F.3d 862, 868 (5th Cir. 2017)). As for "representations regarding the benefits of the BHR's 'as cast' metallurgy," the Court concluded that it was "not until 2015 that Smith & Nephew received data that undercuts its assertions that the BHR's 'as-cast' metallurgy was responsible for a revision rate that was lower that its heat-treated competitors." *Id.*[5] Finally, the Court rejected any claim of a duty "to seek out additional information and disclose it to surgeons" because "any claim that Smith & Nephew had a duty to warn the medical community is preempted." *Sedgwick* Mem. at 20 (citing *In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prods Liab. Litig.*, 300 F. Supp. 3d 732, 745 (D. Md. 2018) ("*In re BHR*")). Summary judgment should be granted to Smith & Nephew here for these same reasons.

[5] Even today, Plaintiffs' expert acknowledges that "some [scientific papers] suggest that wear resistance of as-cast is superior." Deposition of Scott Marshall (Nov. 10, 2020) (Ex. A) at 123.

First, Plaintiffs argue principally that Smith & Nephew should have provided patients and physicians with *additional information* beyond the FDA-approved labeling. *See, e.g.*, Resp. at 7 ("Smith & Nephew failed to include this in any voluntary communications it made to surgeons"); *id.* at 14 ("If Smith & Nephew had provided all of the above pertinent information and the complete picture to the treating physicians, those surgeons would have acted differently."). These arguments are foreclosed because *any claim* based on failure to provide additional or different information "to patients or the medical community" is preempted. *See In re BHR*, 300 F. Supp. 3d at 744–45.

The Court has made clear that a claim of misrepresentation cannot be based on "a duty on Smith & Nephew to seek out additional information and disclose it to surgeons," because any "duty to warn the medical community is preempted." *Sedgwick* Mem. [D.E. 2977] at 20. Thus, failure to publicize information can support a misrepresentation claim in this case only if, in light of the totality of information supplied to a doctor or a physician, Smith & Nephew made a voluntary communication that "create[d] a misleading impression by failing to disclose other known information." *Id.* Plaintiffs' argument fails to satisfy this standard. They do not identify any voluntary communication by Smith & Nephew that left a misleading net impression based on information known to Smith & Nephew, much less show that any specific Plaintiff reasonably relied upon any misleading impression. Thus, any argument that Smith & Nephew failed to disclose such information prior to October 2009 is expressly preempted.

Second, any alleged misrepresentations by Smith & Nephew cannot support liability if they are based upon information that predates FDA's approval of the BHR. As this Court has already ruled, Plaintiffs cannot rely on "information predat[ing] the FDA's PMA approval," because such a claim would seek to "undermine the FDA's PMA approval process." *Sedgwick* Mem. [D.E. 2977] at 18. Thus, Plaintiffs cannot rely upon pre-approval data as a predicate for any alleged

misrepresentation. These arguments are a frontal attack on the FDA's approval decision and would require this Court to reexamine questions committed by statute to the FDA. *See id.*

Third, Plaintiffs do not explain how any alleged misrepresentation from Smith & Nephew differs from the information that FDA expressly approved in the BHR's PMA-approved labeling. In *Sedgwick*, this Court granted summary judgment on claims brought by an early implant patient because, inter alia, (1) Smith & Nephew did not have ad hoc reports at the time of the plaintiff's index procedure *and* (2) other information the plaintiff relied on mirrored statements in the BHR label. *See Sedgwick* Mem. [D.E. 2977] at 17–18. Plaintiffs do not dispute that the first rationale applies to every case at issue in this motion, and they simply ignore the second rationale.

For example, Plaintiffs argue that "Smith & Nephew knew as early as 2006 that the BHR's revision rate in women was much higher than the 1-3% or 2-5% at 10 year revision rate that it trained surgeons." Resp. at 19; *accord id.* at 8, 9 (similar). But as the Court held in *Sedgwick*, statements repeating revision rates taken from the PMA-approved labeling cannot support a misrepresentation claim precisely because they are "consistent with information contained within the BHR's FDA label." *Id.* at 17. Because the FDA "blessed" these statements in the label, *id.* (citing *Wildman*, 874 F.3d at 868), a misrepresentation claim based on statements consistent with what is in the FDA-approved label would constitute "a preempted attempt to undermine the [FDA's] PMA approval process and the FDA-approved BHR label." *Id.* at 18.[6]

[6] It makes no difference that Smith & Nephew acquired some of the information cited by Plaintiffs "after FDA approval of the BHR." Resp. at 2. Once FDA approves a statement, it cannot provide a basis for a misrepresentation claim regardless of what information the manufacturer learns in the interim. *See Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 931 (5th Cir. 2006) (holding the MDA preempted a misrepresentation claim based on statements supported by FDA-approved labeling even where Plaintiff alleged that the manufacturer received new and different data after approval).

B. Plaintiffs' Misrepresentation and Breach of Express Warranty Theories Do Not Support Viable Claims.

None of Plaintiffs' theories of misrepresentation states a viable, non-preempted claim. In their Response, Plaintiffs characterize (but rarely quote) information that they contend Smith & Nephew supposedly had before October 2009 that showed an increased risk of revision in certain patient subpopulations. However, the Court has already considered these arguments and found them insufficient to support a misrepresentation claim. *See infra* § II.B.1. In addition, Plaintiffs' attempt to identify specific, voluntary statements that precede October 2009 fail for myriad reasons, not the least because there is no evidence connecting these statements to any Plaintiff. *See infra* § II.B.2.

1. Plaintiffs Do Not and Cannot Show That Smith & Nephew Had Information Before October 2009 Sufficient to Contradict the Statements in the BHR's FDA-Approved Labeling.

Plaintiffs argue that Smith & Nephew's "actual knowledge about the higher revision risk to women and patients with smaller head sizes of the BHR" before October 2009 was "overwhelming." Resp. at 7. As support, Plaintiffs argue, with 20-20 hindsight, that public data in the Australian Registry before FDA approved of the BHR on May 9, 2006, *id.* (citing 2006 Australian Registry Report), shows a revision rate for women that is the "same as the first ad hoc reports showed for all women receiving a BHR in 2009." *Id.* (citing first ad hoc report received by Smith & Nephew in October 2009). According to Plaintiffs, Smith & Nephew was required to include the revision rate information from the Australian Registry applicable to *all* resurfacing devices in any "communications it made to surgeons" about the BHR. *Id.*

But the BHR label, approved by FDA in May 2006, showed revision rates in men and women that are largely the same. *See* BHR, Important Medical Information [D.E. 3304-4] at 15, Table 15 (98.6% survivorship for males; 98.2% survivorship for females at 5 years). In truth, it

was only in 2011, that the Australian Registry identified "female sex as an independent risk factor for failure." Expert Report of Dr. Michael A. Mont Report (*Quirk*) (Feb. 21, 2022) ("Mont Report") (Ex. B) ¶ 7.[7] Likewise, although metal wear in metal-on-metal devices was known in 2006 when the BHR was approved—and discussed in the 2006 Patient's Guide, which tracks the FDA-approved label, *see* Important Medical Information [D.E. 3304-4] at 4, 5, 6—the term "pseudotumor" was not even coined until mid-2008. Although federal law imposes no duty on Smith & Nephew to provide information to the medical community, it affirmatively did so in a May 2009 Dear Doctor Letter, for which Plaintiffs have identified no legitimate claim of misrepresentation. *See* Mont Report (Ex. B) ¶ 8 ("There is nothing misleading in this letter").[8]

Even accepting Plaintiffs' reading and unsupported characterization of these documents and communications (which Smith & Nephew disputes), they at most show ***some*** evidence that gender or head size (or both) ***might*** be correlated with revision rates—or, even more generally, that metal wear and metal ions in metal-on-metal devices "need[ed] to [be] address[ed]." *See* Resp. at 8–10. Again, the Court has already considered and rejected this precise argument in *Sedgwick*. In that case, as here, Plaintiffs cited "some minimal evidence" that, they claimed, could be read to suggest that "Smith & Nephew had reason to be aware that the overall revision rates it

[7] *See* Hip and Knee Arthroplasty, Annual Report 2011 at 89 ("Previously the Registry has reported that the head size effect explained the gender difference in outcome. This year however for the first time, females have an increased rate of revision independent of head size."), *available at https://aoanjrr.sahmri.com/documents/10180/44800/Annual+Report+2011* (last visited 3/3/22).

[8] The Court recently has suggested that "the superiority of the 'as-cast' metallurgy process," might qualify as a "potentially actionable misrepresentation" for some Plaintiffs generally. *See* Memorandum [D.E. 3496] (Feb. 28, 2022) at 4 & n.6. Even if Smith & Nephew's statements about "as-cast metallurgy" could be shown to be inaccurate—and Smith & Nephew submits that they cannot—that does not assist Plaintiffs who received BHR implants prior to October 2009 because "it was not until 2015 that Smith & Nephew received data that undercut its assertions that the BHR's 'as-cast' metallurgy was responsible for a revision rate that was lower than its heat-treated competitors." *Sedgwick* Mem. [D.E. 2977] at 18.

used to market the BHR to Dr. Boucher overstated the success of the product, particularly for smaller head sizes." *Sedgwick* Mem. [D.E. 2977] at 19. The Court ruled that "a general awareness of the possibility" of increased revision rates for certain patient subpopulations, was an insufficient basis to support a negligent misrepresentation claim. *See id.* at 19-21.

In their Response, Plaintiffs do not introduce any pre-2009 information that suggests Smith & Nephew had any more of an awareness of these issues than the medical community as a whole. In fact, in their effort to explain why the ad hoc reports—up until now, the "crux" of their cases—are not very important, Plaintiffs argue that the information supplied to Smith & Nephew before it received the ad hoc reports was similar to the ad hoc reports, but that the later-supplied reports stated it in a "more granular" or "quantifie[d]" manner. Resp. at 10; *see also id.* (citing communication claiming that 2009 ad hoc reports "confirm[ed] . . . [Smith & Nephew's] suspicions"). Even accepting this characterization, this argument underscores why Smith & Nephew cannot be liable for alleged misrepresentations about revision rates that predate the ad hoc reports. The (newfound) thrust of Plaintiffs' case is that *empirical claims* about the revision rates for the BHR that had been *approved by FDA* were inaccurate. Plaintiffs do not and cannot contend that Smith & Nephew's representations were inconsistent with the information contained in FDA-approved labeling at the time of the implant surgeries for the Plaintiffs at issue here, nor can they assert that those approved statements were undermined by a purported general awareness that lacked any "granular" or "quantifie[d]" basis. *See Sedgwick* Mem. [D.E. 2977] at 19-21.

2. Plaintiffs Have Failed to Identify Any Pre-2009 Voluntary Communications That Were Misleading.

Plaintiffs next identify pre-October 2009 voluntary communications that they claim were misleading. At the outset, none of these communications can create a material dispute of fact for a claim of negligent misrepresentation unless a Plaintiff submits evidence that he or she saw and

relied on any of these statements in deciding to undergo the BHR procedure. If a Plaintiff did not see and rely upon a statement, that statement cannot have caused any injury to the Plaintiff. *See In re Bausch & Lomb Inc. Contacts Lens Sol. Prods. Liab. Litig.*, 693 F. Supp. 2d 515, 520 (D.S.C. 2010) ("causation is a required element in every product[s] liability case"), *aff'd sub nom. Fernandez-Pineiro v. Bausch & Lomb, Inc.*, 429 F. App'x 249, 252-53 (4th Cir. 2011) (per curiam). Moreover, as noted above, Plaintiffs do not identify what additional discovery would be likely to address this critical failure of proof. Even setting aside this fundamental shortcoming, none of the communications cited by Plaintiffs would be a basis for a negligent misrepresentation claim even if a Plaintiff had read and relied upon them.

Plaintiffs point to a Patient's Guide that they previously argued (unsuccessfully) in the *Albritton* case supported a misrepresentation claim. Resp. at 6, 11–12, 13-14. In *Albritton*, the Court held, *inter alia*, that the Patient's Guide could not support a misrepresentation claim because "there is no evidence in the record that Mr. Albritton relied on the Patient's Guide in making the decision to have the BHR implanted," *Albritton* Mem. [D.E. 2962] (Aug. 13, 2021) at 11, and that same shortcoming precludes reliance on the Patient's Guide here.[9]

Further, even if any Plaintiff were to claim to have seen and relied on the Patient's Guide, it was entirely accurate and tracks (and is consistent with) the information in the FDA-approved labeling at the time it was issued. *See* Mont Report (Ex. B) ¶ 2. The Patient's Guide does not contain *any* claims that are false or misleading; and in fact, the Patient's Guide stressed that it "is impossible to say how long your implant will last" and the BHR's bearing surfaces "*may* extend

[9] Even if Plaintiffs had sought to comply with Rule 56(d), *supra* § I, this would not be an appropriate basis to stay Smith & Nephew's motion pending further discovery. The party resisting summary judgment must show why additional discovery is needed, but Plaintiffs cannot show that they need discovery to determine if they received and relied on the Patient's Guide. *See Strag*, 55 F.3d at 954.

its life longer than that of a traditional total hip replacement." Ex. C, at 22 (emphasis added). Further, despite dedicating nearly over a page of their brief to characterizing the Patient's Guide, Plaintiffs identify only one representation that they argue went beyond the FDA-approved labeling: the statement that a BHR revision surgery would be "less 'traumatic and complex' than a total hip revision surgery." Resp. at 12. The actual language refers to the fact that a THA—because it involves removing the natural ball of the femur and driving a stem into the femur bone—is "more traumatic and complex" and "more invasive."[10] In any event, the statement is fully supported by FDA-approved labeling:

> The BHR may make future revision surgery easier because hip resurfacing surgery leaves your femoral head in place and there is no large metal stem placed in the thighbone. Revision surgery of a total hip replacement where your femoral head has already been removed and a large stem is already in place can be a more difficult operation.

E.g., Birmingham Hip Resurfacing (BHR) System, Patient Information (Dec. 2005) (Ex. D) at SN_BHR_MDL_2419119.[11] Smith & Nephew cannot be liable for making a statement that was "blessed" in FDA-approved labeling. *Sedgwick* Mem. [D.E. 2977] at 18.

Next, Plaintiffs assert that a 2009 Dear Doctor letter sent by Dr. Peter Heeckt allegedly downplayed the "risk of pseudotumors," Resp. at 13, but they do not identify what statements they

[10] The language at issue says: "if your surgeon should determine you need to have your BIRMINGHAM HIP implant replaced at some point in the future, you may undergo a regular total hip replacement surgery. If you had originally undergone total hip replacement instead of hip resurfacing, you would be dealing with a more traumatic and complex procedure and you would be receiving a more invasive implant." *See* Patient's Guide (Ex. C) at 14.

[11] The Court recently identified "the supposed greater ease of revision surgery after a BHR than after a THA" as "a potentially actionable misrepresentatio[n] that would be applicable to all patients generally." Memorandum [D.E. 3496] at 4 (citing expert report of Dr. Mont addressing the "***femoral part***" of the revision) (emphasis added). As shown above, that claim is preempted. Further, Dr. Mont has clarified that "revising a resurfacing acetabular cup is easier" than revising a THA because "most cups" for THAs have "screws for standard total hip replacements" whereas resurfacing cups "have no screws and revisions are generally relatively straightforward." Mont Report (Ex. B) ¶ 20.

claim are misleading or tie any such statements to any Plaintiff's case. Plaintiffs omit that the letter expressly brings the issue of pseudotumors, which had been the subject of recent reporting, to the attention of surgeons. Indeed, the letter from Dr. Heeckt highlighted "the issue of benign, inflammatory pseudo-tumors in metal-on-metal hip resurfacing," and noted that Smith & Nephew took the findings of a study "very seriously" and had "started a collaborative effort in order to learn more about the etiology of pseudo-tumors." Resp. Ex. 16, at 1–2.

Finally, Plaintiffs reproduce in their Response an undated, un-cited excerpt purportedly from a Smith & Nephew document that they claim touts the lower revision rate of the BHR and "downplay[s] the risk of metal ions." Resp. at 14. Plaintiffs, however, do not identify any misstatement in the document, nor do they explain how any such misstatement was inconsistent with information known to Smith & Nephew and different from FDA-approved label information. And, in fact, contrary to Plaintiffs' characterization of the document as "downplaying" risks, the excerpt warns of "risks associated with metal-on-metal hip implants," including specifically a "concern[] that the increased level of metal ions found in the blood of metal-on-metal hip recipients may have negative effects on the human body." *Id.*

III. SMITH & NEPHEW IS ENTITLED TO SUMMARY JUDGMENT ON THE CLAIMS FOR WHICH PLAINTIFFS OFFER NO MEANINGFUL RESPONSE.

Plaintiffs do not meaningfully respond to Smith & Nephew's arguments that it is entitled to summary judgment on the claims of early-implant Plaintiffs for failure to warn, negligence *per se*, failure to train, and punitive damages. SJ Mem. at 12-17 (failure to warn); *id*. at 17-18 (negligence *per se*); *id.* at 26-27 (failure to train); *id.* at 28-29 (punitive damages). Plaintiffs simply argue that such claims are, *in theory*, viable, but make no attempt to connect those theories to the claims of Plaintiffs who received the BHR prior to October 2009. Smith & Nephew is therefore entitled to summary judgment on these claims. *See Ferdinand-Davenport*, 742 F. Supp. 2d at 777

(Blake, J.) ("failure to respond" to arguments raised in summary judgment motion "abandons" those claims); Mem. [D.E. 3496] at 5-6 (same).

A. Smith & Nephew Is Entitled to Summary Judgment on Plaintiffs' Claims for Failure to Warn the FDA.

This Court has already dismissed any claim that Smith & Nephew had a duty to warn "patients or the medical community" beyond the warnings included in the FDA-approved BHR labeling. *See In re BHR*, 300 F. Supp. 3d at 745. Further, in light of the Plaintiffs' "appropriately . . . disavow[ing] any arguments concerning discretionary actions the FDA may or may not have taken," *Redick* Mem. [D.E. 2715] at 16, the Court has held in every case to reach summary judgment that Plaintiffs cannot established causation. *See, e.g.*, *id.* at 16–18; *Albritton* Mem. [D.E. 2962] at 8–9; *Mosca* Mem. [D.E. 2905], at 15–16; *Sedgwick* Mem. [D.E. 2977] at 13–14; *see also* Mem. [D.E. 3496] at 5-6 (same). Plaintiffs still do not, and cannot, point to any "actions the FDA may or may not have taken" that would support a causal chain between a purported failure to report information to FDA and their alleged injuries. Moreover, that causation bar, which is "difficult" to meet in any case, *e.g.*, *Redick* Mem. [D.E. 2715] at 16, is impossible to meet for Plaintiffs who underwent the BHR procedure before October 2009, because they identify nothing that Smith & Nephew had to report to FDA at the time. *See Sedgwick* Mem. [D.E. 2977] at 13 (granting summary judgment on failure to warn claim "predicated on the failure to disclose to the FDA ad hoc data and reports that Smith & Nephew received after Sedgwick's surgery") (emphasis omitted).

Plaintiffs' reliance on public information predating October 2009 does not create a triable question of fact. None of the information relied upon by Plaintiffs in their Response was inconsistent with what Smith & Nephew said publicly or what FDA approved. But more fundamentally, all of the Australian Registry data relied upon by Plaintiffs here was *public*

information.[12] As this Court explained in *Sedgwick*, Plaintiffs' theory of causation for failure to warn the FDA requires "showing that information or data Smith & Nephew was required to provide to the FDA *would necessarily have been made public*." *Sedgwick* Mem. [D.E. 2977] at 13 (emphasis added); *see also id.* at 13–14 (Plaintiffs must identify information that "*if publicized*, would have reached [Plaintiffs' physicians]") (emphasis added); *accord Redick* Mem. [D.E. 2715] at 16 (Plaintiffs must show that "ad hoc data provided to the FDA would necessarily have been made public"). Because the information was already *public*, any alleged failure to report it to the FDA could not have caused Plaintiffs' injuries. Indeed, Plaintiffs' own experts could not identify any pre-October 2009 information that should have been, but was not, provided to FDA. *See* Deposition of Larry Spears (Sept. 8, 2020) (Ex. F) at 142-43 (Q: "[H]ave you identified anything else outside of this document from the 2007 to 2008 time period that the company failed to provide to FDA in violation of an FDA requirement?" A: "The answer to that is no"); *id*. at 139 (agreeing that "the 2007 and 2008" data "wouldn't be something they'd have to [report to FDA] under PMA Condition No. 4 or – or otherwise" under FDA regulations); Expert Report of Mari Truman, MS, PE (MDL) (July 15, 2020) (Ex. G) at 31 (contending 2009 registry data "should have been provided to the FDA"); *id*. at 57 (showing no "sub-population rate" registry data prior to 2009).

[12] Plaintiffs contend that "Smith & Nephew never informed the FDA that the revision risk for women and smaller head sizes was significantly higher than the overall revision rate, and in fact told FDA the opposite." Resp. at 18 (citing Plaintiffs' Response to S&N's Motions to Exclude Expert Opinions [D.E. 2427] at 23-28). The citation identified by Plaintiffs is to an index of documents, and Plaintiffs make no effort to identify the information within those documents that they contend supports their claims. In fact, Smith & Nephew submitted annual reports to FDA, which each year were approved by FDA. As explained by Donna-Bea Tillman, the information provided by Smith & Nephew included information and summaries from the Australian Registry. Expert Report of Donna-Bea Tillman, Ph.D., MPA, FRAPS, Expert Report (Aug. 28, 2020) (Ex. E) at 34-40.

Plaintiffs' only response is to contend that failure to warn the FDA claims are "viable." Resp. at 18. The question is not whether *a* plaintiff *could* prevail on a failure to warn claim, but rather whether there is any evidence that would support *these specific Plaintiffs'* claims. Plaintiffs do not identify any such evidence, nor do they even explain what types of evidence they could supply that would create a triable question of fact. Therefore, summary judgment should be granted on the failure to warn claim as to all Plaintiffs subject to this motion.

B. Smith & Nephew Is Entitled to Summary Judgment on Plaintiffs' Claims for Negligence *Per Se* and Negligent Surgeon Training.

Because Smith & Nephew is entitled to judgment on Plaintiffs' negligent misrepresentation and failure to warn claims, their negligence *per se* claims necessarily fail as well. Plaintiffs do not dispute this. *See* Resp. at 18 (admitting that negligence *per se* claim is based on "misrepresentations and failure to report to the FDA"); *see also, e.g.*, *Redick* Mem. [D.E. 2715] at 27 (finding that plaintiff's negligence *per se* claim "suffers from the same causal deficiencies as the plaintiffs' failure to warn claim"). In their Response, Plaintiffs suggest in passing that they can support a negligence *per se* claim based on "misbranding claims arising from misrepresentations and failure to report to the FDA." Resp. at 18. Plaintiffs do not engage at all, however, with Smith & Nephew's showing or the Court's prior ruling that a "misbranding" theory is preempted because it is a challenge to the FDA-approved device label. *See Redick* Mem. [D.E. 2715] at 29–31.

Similarly, Plaintiffs do not identify any statements made in BHR training before October 2009 that can support a failure-to-train claim—much less connect any of those statements to training attended by their implanting physicians. Instead, Plaintiffs contend that Smith & Nephew was required to *change* its training program to include additional information that contradicted the FDA-approved labeling. Resp. at 19. That argument disregards this Court's repeated

determination that federal law preempts any claim that Smith & Nephew "had a duty to change its program" because such a claim "would add to or differ from the requirement to merely implement the program." *Redick* Mem. [D.E. 2715] at 29; *see also id.* ("Once the FDA approved the training program, there appears to have been 'no requirement to make updates to that program.'").

C. Smith & Nephew Is Entitled to Summary Judgment on Plaintiffs' Claims for Punitive Damages.

Finally, Plaintiffs do not meaningfully join issue on Smith & Nephew's showing that punitive damages are not available, as a matter of law, for plaintiffs who received the BHR before October 2009. Plaintiffs do not dispute that punitive damages is a remedy and not an independent cause of action, *see In re BHR*, 300 F. Supp. 3d at 736 n.3, and therefore the claim for punitive damages necessarily fails where, as here, Plaintiffs' substantive causes of action are not viable. Plaintiffs instead fall back on their generic case theme of profits over patients, *see* Resp. at 19 (citing a document calling the BHR a "cash cow"), but there is nothing wrong, much less worthy of punitive damages, about a company seeking to make money from a medical device that was approved by FDA under a rigorous pre-market approval process, and remained approved at the time of the implant surgeries for all of the Plaintiffs at issue here. Plaintiffs cannot establish that Smith & Nephew engaged in the sort of conduct necessary to support punitive damages.

CONCLUSION

For these reasons, summary judgment should be granted to Smith & Nephew as to the remaining claims of the implanted with a BHR device prior to October 2009.

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Respectfully Submitted,

/s/ Paul J. Zidlicky

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CERTIFICATE OF SERVICE

I, Paul J. Zidlicky, hereby certify that on this 4th day of March, 2022, I electronically filed the foregoing with the Court using the CM/ECF system, and thereby delivered the foregoing by electronic means to all counsel of record.

/s/ Paul J. Zidlicky
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